

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO: WAVE 2 CASES	Master File No. 2:12-MD-02327 MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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**REPLY IN SUPPORT OF PLAINTIFFS' MOTION
TO EXCLUDE THE OPINIONS OF DR. SHELBY THAMES**

In further support of their Motion to exclude certain opinions and testimony of Defendants' expert, Dr. Shelby Thames ("Dr. Thames"), Plaintiffs state as follows:

INTRODUCTION

Dr. Shelby Thames is eager to defend Ethicon's Prolene material in these cases, but without reliable scientific support, his opinions cannot be allowed at trial. Ethicon's Response to Plaintiffs' Motion provides no explanation for many of the complaints that Plaintiffs have regarding Dr. Thames' Wave 2 opinions and report. Ethicon does not dispute that Dr. Thames should be prevented from testifying that Prolene does not degrade inside the body. Ethicon does not dispute that Dr. Thames should be prevented from testifying that no molecular weight changes were recorded internally or by Plaintiffs' expert Dr. Jordi. Ethicon does not dispute that Dr. Thames' dog study-based "toughness" opinions have no statistical significance, and therefore, cannot be applied to all of the women implanted with Prolene mesh. And Ethicon does not dispute that if Dr. Thames' cleaning protocol actually destroys evidence of oxidation on

Plaintiffs' meshes then his opinions on the presence of extrusion lines and colored flakes have absolutely no support behind them.

What Ethicon's Response does do, however, is rely heavily on opinions and texts that are not part of Dr. Thames' Wave 2 report or reliance list. His report needs to stand on its own—and it does not. These additional materials and arguments aside, Dr. Thames' Wave 2 report contains self-contradictory opinions, it lacks support from the scientific literature and scientific method, and it mischaracterizes the available evidence to fit his opinions. As such, Plaintiffs' Motion should be granted in full and the additional materials referenced in Ethicon's Response—and Ethicon's arguments based upon them—should be stricken.

ARGUMENT

Many of the opinions in Dr. Thames' Wave 2 report are *ipse dixit* and he can find no support for them in the scientific community or even internally at Ethicon—including from Ethicon's *in vivo* corporate designee, Dr. Thomas Barbolt. Dr. Thames should be prevented from offering opinions lack scientific merit and are at odds with the admissions of Ethicon's corporate designee.

According to Dr. Thames, his opinions are based on his personal investigations into explanted Prolene mesh, the seven year internal dog study, and the material referenced in his reliance list and report.¹ But this is not enough in this case. Dr. Thames' personal investigations with explanted Prolene mesh employed a cleaning protocol that would have destroyed any surface degradation that was on Plaintiffs' meshes—so he cannot rely on the results of that testing as a basis for any of his opinions here. Additionally, he misstates the molecular weight results of the internal dog study to fit his opinions, and therefore, his opinions cannot satisfy the rigors of the Court's *Daubert* inquiry and must be excluded. Finally, much of the material that

¹ Ex. A, Thames Wave 2 report at 120-122

Ethicon references in an attempt defend Dr. Thames' opinions does not appear in any of Dr. Thames' reliance material or report. As such, it should all be stricken and not considered by the Court for this *Daubert* determination.

1. Ethicon does not dispute that Dr. Thames should be prevented from testifying that Prolene does not degrade inside the body.

The duty rests with Dr. Thames to proffer expert testimony and “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). He has not done that in his Wave 2 report in many instances. The first relates to his opinion that Prolene does not degrade inside the body. In an attempt to focus the contents of Dr. Thames' report before trial, Ethicon's Response endeavors to define what his opinion is on this issue:

“Dr. Thames's opinion: Plaintiffs have not shown that Prolene undergoes meaningful degradation in vivo because there is no scientifically valid data to support the claim that Prolene oxidizes or degrades in the human body.”²

This opinion comes from Ethicon's counsel—not Dr. Thames—and is not specifically stated in his report. Importantly, however, Ethicon does not argue that Dr. Thames should be allowed to testify that Prolene does not degrade inside the body; it just argues that he should be allowed to discredit the peer reviewed literature, known principles of polymer science, and all of the internal work done on Prolene's oxidation—including that of Ethicon's corporate designee, Dr. Thomas Barbolt.³

Plaintiffs seek to exclude all of Dr. Thames' Prolene-based oxidation opinions because they are unreliable and without support in the scientific community. But at a minimum, because Ethicon's Response admits that Dr. Thames will not be opining that Prolene does not degrade inside the body—that opinion must be excluded from trial.

² Defs.' Br. at 2

³ *Id.*

There is a big difference between Dr. Thames opining that Prolene does not degrade inside the body and “Plaintiffs have not shown that Prolene undergoes meaningful degradation *in vivo*.” Dr. Thames has nothing to support an opinion that Prolene does not degrade *in vivo*—the peer reviewed literature says it does, the internal studies say it does, and all of Dr. Thames’ personal investigations with explanted mesh are tainted by his cleaning protocol’s destruction of the outer layer of degraded material. And again, Ethicon does not argue that Dr. Thames should be able to hold this opinion at trial. It must be excluded.

2. Ethicon does not dispute that Dr. Thames should be prevented from testifying that no molecular weight changes were recorded internally by Ethicon, or by Plaintiffs’ experts.

Similarly, Dr. Thames’ choice of words on the witness stand matters; he should be prevented from telling a jury that no molecular weight changes or losses were measured for Prolene *in vivo*—either internally at Ethicon or by Plaintiffs’ experts. Plaintiffs note that Dr. Thames’ Wave 2 report has been altered from his Wave 1 report to remove several instances where it previously (and incorrectly) stated that the Burkley dog study found *no changes* in molecular weight. However, Dr. Thames’ Wave 2 report still states:

“both Burkley and Jordi independently determined unequivocally that Prolene does not degrade (no MW loss) *in vivo*. Therefore, no degradation of Prolene occurs in-vivo, as molecular weight loss is a form of degradation, i.e. no degradation, no molecular weight loss.”⁴

This is not a true statement—and Ethicon does not dispute that fact in its Response. Indeed, Ethicon cannot dispute the inaccuracy of Dr. Thames’ statement because its own corporate

⁴ Ex. A, Dr. Thames Wave 2 General report at 29

designee knows the real truth, as does Dr. Jordi, and all of the internal documents and studies show the same thing.^{5, 6}

There is a big difference between Dr. Thames stating that, in his *opinion*, “no significant loss in molecular weight was found” and him making the factually incorrect statement that “no changes or losses in molecular weight were found”—his Wave 2 report says both, but only one can be considered valid. As such, and because Ethicon does not argue otherwise, he must be prevented from stating that no losses or changes of molecular weight have been reported for Prolene *in vivo*.

3. Ethicon does not dispute that Dr. Thames’ dog study-based ‘toughness’ opinions have no statistical significance, and therefore, cannot be applied to all of the women implanted with Prolene-based meshes.

In the same vein, Dr. Thames’ toughness opinions must also be excluded. First, Dr. Thames bases his toughness opinions on his incorrect assertion that there was no molecular weight changes or losses found in the Burkley dog study.⁷ As stated above, this is not a true statement and, therefore, his toughness opinions lack foundation in the scientific method.

Second, Ethicon’s Response argues that Dr. Thames’ toughness opinions are valid, but it points to literature that does not appear on his reliance list or in his report.⁸ These references should be stricken and not considered by the Court. Dr. Thames has the obligation to show that the opinions described in his report have scientific support and he has not done that.

⁵ Ex. B, ETH.MESH.05453719; Ex. C, Deposition of Dan Burkley, May 22, 2013 at 154:22-155:1; ; See also Ex. D, Barbolt Dep., 1/8/2014, at 409:2-13, 360:20-25, 396:2-233, 85:14-20

⁶ Ex. A, Thames report at 31-38.

⁷ Ex. F, Thames Dep. at 135:21-136:12 (emphasis added)

⁸ Gere & S. Timoshenko, *Mechanics of Materials*, 14 (1997) does not appear in Dr. Thames reliance; *see also* Def’s Brief at 14.

Additionally, the Response also states that Dr. Thames plotted the dog study data from years' 0, 1, 2, and 7 to create a stress-strain curve, but that information is not in his report.⁹ Dr. Thames' report only shows two data plots from the dog study: one from year zero and one from year seven.¹⁰ Neither of these lines represents a stress/strain curve—they can't even be considered a curve because they are just two data points with lines connected to zero.

Plaintiffs have no way of knowing how Dr. Thames' toughness opinions were formed. His report does not have the data in it, the graphs in his report do not show a stress/strain curve, and he cannot falsely state that there were no losses in molecular weight recorded in the dog study as a foundation for his findings. All of his toughness opinions must be excluded.

Moreover, Dr. Thames wants to testify that he looked at the data from six explanted Prolene sutures and saw that those sutures lost all of their mechanical properties inside the body, but that they didn't degrade—even though Ethicon's Response defines degradation as being losses in mechanical properties.¹¹ And even if one assumes, *arguendo*, that Dr. Thames' toughness opinions have merit, there is no statistical significance from the dog study to infer that all Prolene sutures would behave the same way, and there is certainly nothing to support an opinion that the Prolene meshes implanted into the Plaintiffs would behave in the same way either. Ethicon never even addresses Plaintiffs' concerns over a lack of statistical significance here. All of his toughness opinions must, therefore, be excluded from trial as unscientific, unreliable, and completely unsupported.

4. Ethicon does not dispute that if Dr. Thames' cleaning protocol actually destroys evidence of oxidation on Plaintiffs' meshes then his opinions on the presence of extrusion lines and colored flakes have absolutely no support.

⁹ Def's Brief at 13; *See also* Ex.A, Thames report at 7-9

¹⁰ Ex.A, Thames report at 7-9

¹¹ Def's Brief at 2, FN1

There is nothing in the peer-reviewed literature to support Dr. Thames' opinions on the presence of extrusion lines and translucent flakes on explanted materials—and he came to these conclusions by employing a cleaning protocol that destroys evidence of oxidation on explanted mesh. And even if Plaintiffs assume, *arguendo*, that Dr. Thames' cleaning protocol did not destroy evidence of oxidation, his opinions regarding clear or translucent flakes and extrusion lines still have *no* support in the literature. In fact, Dr. Thames did not even try to find support in the literature for these opinions.¹²

Nevertheless, Dr. Thames' opinions on these two issues are the tainted result of his employing a cleaning protocol that is untested and unexplained. The steps of that cleaning protocol include the use of Proteinase-K, sonication and shaking, water, heat and bleach—all of which could have destroyed evidence of surface oxidation, but Dr. Thames did not determine what effect, if any, the steps of his cleaning protocol had on oxidized Prolene.¹³ He *assumed* there would be none even though the peer reviewed literature from 1998 described that stresses like shaking and sonication would remove the outer degraded layer from explanted Prolene:

“Because this cracking is confined to the outer skin, which is clearly distinguishable from the inner core structure, it is not surprising to observe that, during abrasive stresses, such as cleaning, there was a tendency for the cracked rings at the surface to flake off and separate from the underlying core material.”¹⁴

Dr. Thames should not be allowed to base any opinions or testimony on this tainted protocol. He did not run a proper control and he should have known that his cleaning methods would destroy evidence of oxidation.

¹² Ex. G, Thames deposition for the Shelton case at 30:9-35:13; *See* also Ex H. Thames deposition for the Johnson case at 37:5-22.

¹³ Ex. I, Dr. Thames Deposition in the Stubblefield case at 64:7-23; Ex. J, Dr. Thames Deposition in the Daino case at 21:3-16

¹⁴ Ex. K, Celine Mary, Yves Marois, Martin W. King, Gaetan Laroche, Yvan Douville, Louisette Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, *ASAIO Journal*, 44 (1998) 199-206

5. The additional materials referenced in Ethicon’s Response should not be considered by the Court in this *Daubert* inquiry.

Ethicon’s Response points the Court to opinions and materials that are not part of Dr. Thames’ Wave 2 report.¹⁵ Ethicon also claims that Drs. Ong and Thames plan to publish and present a paper describing what they call the myth of polypropylene degradation—and that peer-review for that paper has already begun.¹⁶ To be clear, to date, nothing has been published or presented, and no specific experiment or study has been done by Drs. Ong and Thames for this planned paper or presentation.¹⁷ They merely collected the information and data that has been submitted as their expert materials in this litigation and are prepared to talk about it at a presentation and hoping to publish it someday.¹⁸ But there is no guarantee that this paper will ever be published. Indeed, the peer-review process contains a series of questions and comments from reviewers before deciding if a paper can be published—and that is the current stage (pre-publication) of this paper that Ethicon seeks to use to bolster Dr. Thames’ opinions.¹⁹

In any event, Dr. Thames’ Wave 2 report needs to stand on its own. Ethicon’s Response not only includes a supplemental report from Dr. Thames, but it adds an affidavit from him, and numerous references to materials that do not appear on his reliance list. All of this material should be stricken and not considered by the Court at this stage.

CONCLUSION

For the foregoing reasons, Dr. Thames should be limited in what he can testify about in these Wave 2 cases. No jury should ever hear any evidence that is unreliable—and Dr. Thames’ *ipse dixit* and factually unsupported opinions should be precluded. In addition, he has no basis to

¹⁵ Def’s Brief, generally

¹⁶ *Id.*

¹⁷ Ex L, Dr. Thames deposition in the Martin case at 109:17-112:9.

¹⁸ *Id.*

¹⁹ *Id.*

offer any case-specific opinions because his cleaning protocol destroyed whatever evidence of oxidation was originally on the meshes that he examined. Finally, all additional materials, not contained in Dr. Thames' Wave 2 report should be stricken and not considered at this time.

Plaintiffs respectfully request their Motion be granted.

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CERTIFICATE OF SERVICE

I hereby certify that on August 18, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Edward A. Wallace

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